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5. 510(k) SUMMARY

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Lisa Giaquinto, Sr. Regulatory Affairs Analyst
Phone: (610) 596-2536
Fax: (610) 266-4962
E-mail: Lisa.Giaquinto@bbraun.com

DEVICE NAME: Prontosan™ Wound Gel

COMMON OR USUAL NAME: Wound Cleanser, Wound Dressing

DEVICE CLASSIFICATION: Class II, Product Code FRO, Unclassified

PREDICATE DEVICES: Prontosan™ Wound Irrigation Solution
B. Braun Medical, Inc.
Regulatory Class: Unclassified, Product Code: FRO
510(k) K072876, June 19, 2008

DESCRIPTION: Prontosan™ Wound Gel is a clear, colourless liquid-gel containing undecylenamidopropyl betaine, polyaminopropyl biguanide, glycerol, hydroxyethylcellulose and purified water. Prontosan™ Wound Gel is used for managing and treating wounds by sustaining wound moisture between dressing changes and aiding in the manual removal of wound exudates and encrustations. The gel is aseptically filled using a blow fill seal process into low density polyethylene 30 mL squeeze bottles with screw caps.

INTENDED USE: Prontosan™ Wound Gel is intended for moistening and cleansing wounds by maceration of wound coatings and for moistening and lubricating absorbent wound dressings for ulcers, burns, post-surgical wounds, and abrasions.

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SUBSTANTIAL EQUIVALENCE:

The proposed device and the predicate device are both intended for the cleansing and moistening of wounds. Both Prontosan™ Wound Gel and Prontosan™ Wound Irrigation Solution use the same active ingredients, and only differ in formulation by the presence of the inactive ingredients: hydroxyethylcellulose and glycerol, which have been added for the purpose of providing viscosity and moisturizing properties to the formulation.

The safety and effectiveness of Prontosan™ Wound Gel is supported by biocompatibility testing, USP <51> Antimicrobial Effectiveness Testing, USP <85> Bacterial Endotoxin testing, and shelf life testing. Biocompatibility and performance testing conducted with Prontosan™ Wound Gel demonstrates that there are no new issues of safety or effectiveness for the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2009

B. Braun Medical, Inc.
% Ms. Lisa Giaquinto, RAC
Regulatory Affairs Analyst
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

Re: K090141
Trade/Device Name: Prontosan™ Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 16, 2009
Received: January 21, 2009

Dear Ms. Giaquinto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

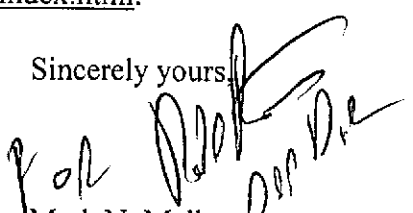
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090141

Device Name: Prontosan™ Wound Gel

Indications For Use: Prontosan™ Wound Gel is intended for moistening and cleansing wounds by maceration of wound coatings and for moistening and lubricating absorbent wound dressings for ulcers, burns, post-surgical wounds, and abrasions.

Prescription Use X AND/OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM March 16, 2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090141